NONINVASIVE TRANSDERMAL SYSTEMS FOR DETECTING AN ANALYTE IN A BIOLOGICAL FLUID AND METHODS

Abstract

The present invention relates to noninvasive transdermal systems and methods for analyte extraction from a biological fluid within or beneath the skin, such as interstitial fluid, and detection of the analyte. More particularly, the present invention relates to noninvasive transdermal systems comprised of a noninvasive transdermal patch and a reflectometer. The noninvasive transdermal patches are comprised of a wet chemistry component and a dry chemistry component. The wet chemistry component is a liquid transfer medium in the form of a gel layer for the extraction and liquid bridge transfer of the analyte of interest from the biological fluid within or beneath the skin to the dry chemistry component. The dry chemistry component is a super sensitive or conditioned membrane carrying a reagent system for interacting with the analyte of interest to generate an indicator molecule, e.g., color change, to confirm detection of the analyte, and methods of use thereof. The indicator molecule may be visually observed by the individual user or observed by an electronic interpretation component, such as a reflectance spectrophotometer for detection. A particular analyte of interest which may be detected accurately, reliably and quantitatively in accordance with the present invention is glucose. The noninvasive transdermal systems of the present invention are low in-cost and suitable for convenient use by non-medical personnel.

The reflectometers include a modulated light source for emitting light to illuminate a target surface which possesses a certain color and shade of color. Light that is reflected from the target surface is detected by an optical detector. The output from the optical detector is processed and fed back to the optical detector to compensate for any shift caused by ambient light, temperature or other external factors, and is differentially amplified to generate an output signal indicative of the color

and shade of the target surface. The output signal from the differential amplifier is then demodulated by a synchronous detector to produce a substantially steady DC voltage that is indicative of the color or shade of color at the target surface. Where the target surface color shade is indicative of a certain measurable quantity or quality (such as an analyte concentration), the steady DC voltage is converted using a look-up table or mathematical formula into a corresponding quantity or quality measurement. In performing this conversion, compensation is made for any variations in modulated light source intensity due to temperature change.